REMARKS

Claims 32, 34, 37, 39, 41, 42, 45-47, and 55-60 are currently pending in the present application.

§ 112, second paragraph

Claims 57 and 59 stand rejected under 35 USC § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. This rejection is respectfully traversed.

The Office has specifically asserted that the term "sufficient" in claim 57 is a relative term which renders the claim indefinite. However, considering claim 57 as a whole, claim 57 actually recites "sufficient to have antimicrobial activity" and this is a generally accepted pharmaceutical phrase. Furthermore, this phrase cannot be read in a vacuum, but must be considered in light of the specification. In this context, those of ordinary skill in the art will understand that the phrase "sufficient to have antimicrobial activity" refers to the minimum inhibitory concentration (MIC). The MIC is the minimum concentration of the antibacterial agent in a given culture medium below which bacterial growth is not inhibited. Tables 1A-D, 2, 3A-B, 4A-C and 5A-C disclose MIC data for organisms against different formulations of EDTA.

According to MPEP § 2173.02, in reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the Office must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. See, e.g., *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) ("The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles. Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite.").

The phrase "sufficient to have antimicrobial activity" in claim 57 is not indefinite to one skilled in the art and is properly supported by the present specification. Accordingly, applicants respectfully request that the rejection of claims

57 and 59 under 35 USC § 112, second paragraph, as allegedly being indefinite, be withdrawn.

§ 103(a) – Fahim in view of Wider

Claims 32, 34, 39, 41, 42, 45, and 55-60 stand rejected under 35 USC § 103(a) as allegedly being obvious over Fahim (WO 00/13656) in view of Wider (US 6,500,861). This rejection is respectfully traversed.

Representative claims 32, 56 and 57 recite that the compositions are packaged in a sterile, non-pyrogenic form. Because the compositions are packaged in a sterile, non-pyrogenic form, the compositions may be safe and biocompatible, at least in modest volumes in a patient's bloodstream. Providing compositions packaged in a sterile, non-pyrogenic form typically requires special processing procedures for both packaging components and solution components. These procedures can be expensive and time consuming. For example, care must be taken with regard to multiple potential sources for pyrogens, e.g., water used as a solvent or in processing, packaging components, raw materials, and equipment used.

Fahim relates to an antimicrobial handwash composition and does not teach or suggest that the composition is packaged in a sterile, non-pyrogenic form which the Office expressly concedes at the top of page 5 of the Action.

The Office relies on Wider to allegedly remedy this deficiency, arguing that it would have been obvious to one skilled in the art to employ the antimicrobial composition of Fahim in a sterile, pyrogen-free condition because Wider allegedly teaches antimicrobial compositions packaged in a sterile, pyrogen-free form. The Office asserts that Wider teaches antimicrobial compositions for eliminating infection from the surface of the body. However, as specifically disclosed in the passage beginning at column 5, line 50, Wider teaches that the composition is for "internal spaces" and expressly states:

> It is also contemplated that the present compositions be used for the elimination of microorganisms from exposed body tissues that ***normally are not exposed***, such as the skin and underlying structure exposed by trauma or incision for or during surgery, or because of the introduction of surgical instruments or other such devices, such as vascular catheters and the like.

(Emphasis added).

A specific application of the composition is as an adjunct to peritoneal dialysis where there is a risk of infection of the abdominal cavity. It is for this reason that Wider teaches at column 6, lines 5-11 (a passage relied on by the Examiner) that hypertonic dialysis fluid should be in "sterile and pyrogen free" form.

Fahim, on the other hand, is focused on an antimicrobial handwash composition. See, e.g., Abstract and Field of Invention ("the invention relates to liquid antimicrobial handwash compositions"). Needless to state, a handwash composition is specifically designed to treat exposed skin surfaces. As may be seen from Example 11, when the composition is placed in the eye of a rabbit, ocular irritation in the form of corneal opacity and conjunctivitis occurred.

One skilled in the art would not be motivated by the teaching of a sterile, pyrogen-free composition for body tissues that are normally not exposed (particularly a hypertonic dialysis fluid designed for peritoneal dialysis) to modify a handwash composition. A handwash composition is not intended for potential contact with a patient's bloodstream or to otherwise be possibly introduced into the "internal spaces" of a patient's body. A handwash is simply meant to cleanse the skin. Thus, there is no reason for one skilled in the art to package a handwash in a sterile, non-pyrogenic form because, for example, a handwash does not typically come into contact with a user in a manner where packaging in a sterile, non-pyrogenic form would be beneficial. One skilled in the art would not be motivated by a teaching of a sterile, pyrogen-free composition that is designed for body tissues that are normally not exposed ("internal spaces"). To then undergo the extra time and expense to package a handwash in a sterile, non-pyrogenic form would not only not be obvious, it would actually be contrary to the teachings of Wider to use the disclosed compositions on body tissue that is not normally exposed.

Further, applicants traverse the assertion that Fahim allegedly teaches that the EDTA salt provides at least 50% of a total antimicrobial activity of the composition. Fahim teaches a composition comprising three primary antimicrobial components, triclosan, PCMX and glutaraldehyde. An EDTA salt is not a required component as is evident from the first description embodiment on page 5. Fahim teaches that EDTA is simply added as an enhancer to these primary antimicrobial components. See Page 10, lines 26-31. Indeed, Fahim does not teach that EDTA salt alone has any antimicrobial properties. Accordingly, Fahim does not teach or

suggest that the EDTA salt provides at least 50% of a total antimicrobial activity of the composition and would actually lead away from this aspect of applicants' invention.

Accordingly, applicants respectfully request that the rejection of claims 32, 34, 39, 41, 42, 45, and 55-60 under § 103(a) as being obvious over Fahim in view of Wider, be withdrawn.

§ 103(a) – Fahim in view of Wider and further in view of Root et al.

Claim 47 stands rejected under 35 USC § 103(a) as allegedly being obvious over Fahim (WO 00/13656) in view of Wider (US 6,500,861) and further in view of Root et al. This rejection is respectfully traversed.

Claim 47 depends from any of claims 32, 56 or 57 and further recites that the composition is in a single-dosage vial.

As addressed above, one skilled in the art would not be motivated by Wider to modify Fahim in order to arrive at the presently claimed invention and there would be even less motivation to package a handwash composition in a single-dosage vial.

To then attempt to rely on Root et al., which relates to a catheter flush solution, to further modify the handwash composition of Fahim would be far outside the realm of obviousness and could only be justified by improper resort to applicants' own specification and claims.

Accordingly, applicants respectfully request that the rejection of claim 47 under § 103(a) as being obvious over Fahim in view of Wider and further in view of Root et al., be withdrawn.

§ 103(a) – Fahim in view of Wider and further in view of Remington's Pharmaceutical Sciences

Claim 46 stands rejected under 35 USC § 103(a) as allegedly being obvious over Fahim (WO 00/13656) in view of Wider (US 6,500,861) and further in view of Remington's Pharmaceutical Sciences. This rejection is respectfully traversed.

Claim 46 also depends from any of claims 32, 56 or 57 and further recites that the composition is in a pre-filled syringe. As again addressed above, one skilled in the art would not be motivated by Wider to modify Fahim in order to arrive at the presently claimed invention.

The Examiner relies on excerpts from Remington's Pharmaceutical Sciences, teaching a pyrogen free solution of sodium chloride and that hypodermic syringes are used for injection of liquids. See Remington's Pharmaceutical Sciences, page 835, column 2, and page 1837. The sodium chloride solution is disclosed to be an electrolyte replenisher administered intravenously.

Fahim, on the other hand, is focused on an antimicrobial handwash composition. See, e.g., Abstract and Field of Invention ("the invention relates to liquid antimicrobial handwash compositions"). One skilled in the art would not be motivated by the teaching of a sterile, pyrogen-electrolyte replenisher to modify a handwash. A handwash is again not intended for potential contact with a patient's bloodstream or to otherwise be possibly introduced into a patient's body. A handwash is simply meant to cleanse the skin. Thus, there is no reason for one skilled in the art to package a handwash in a sterile, non-pyrogenic form because, for example, a handwash does not typically come into contact with a user in a manner where packaging in a sterile, non-pyrogenic form would be beneficial. One skilled in the art would not be motivated by a teaching of a sterile, pyrogen-free electrolyte replenisher to then undergo the extra time and expense to package a handwash in a sterile, non-pyrogenic form. Furthermore, there would be absolutely no reason to package a handwash composition in a pre-filled syringe as expressly recited in claim 46.

Accordingly, applicants respectfully request that the rejection of claim 46 under § 103(a) as being obvious over Fahim in view of Wider and further in view of Remington's Pharmaceutical Sciences, be withdrawn.

§ 103(a) – Kurginski in view of Fahim and in view of Wider

Claims 32, 34, 37, 41, 42, 45, and 55-60 stand rejected under 35 USC §103(a) as allegedly being obvious over Kurginski (GB 1 279 148) in view of Fahim (WO 00/13656) and in view of Wider (US 6,500,861). This rejection is respectfully traversed.

Kurginski is focused on "a cleaning composition useful for releasing the particular soils that tend to accumulate in toilets and similar sanitary facilities." Kurginski, page 1, lines 12-15. As conceded by the Office on page 8 of the Action,

Kurginski does not teach or suggest that the antiseptic composition is packaged in a sterile, non-pyrogenic form.

The Office relies on Fahim and Wider to attempt to remedy this substantial deficiency, alleging that it would have been obvious to one skilled in the art to employ the composition of Fahim in a sterile, pyrogen-free condition because Wider allegedly teaches antimicrobial compositions packaged in a sterile, pyrogen-free form.

However, one skilled in the art would not have been motivated to incorporate the teachings of Wider into the composition of Fahim.

The Office asserts that Wider teaches antimicrobial compositions for eliminating infection from the surface of the body. However, this use is for "exposed body tissues that ***normally are not exposed***, such as the skin and underlying structure exposed by trauma or incision for or during surgery, or because of the introduction of surgical instruments or other such devices, such as vascular catheters and the like." Column 5, lines 56-62 (emphasis added). One skilled in the art would clearly not be motivated to package a toilet cleaning composition in a sterile, non-pyrogenic form, as recited in each and every one of the independent claims of record. A cleaning composition for toilets and similar sanitary facilities is not intended for potential contact with a patient's bloodstream or to otherwise be possibly introduced into a patient's body and there is no motivation to package such a cleaning composition in a form that is sterile and non-pyrogenic. Moreover, one skilled in the art would not be motivated by the teaching in Wider of a sterile, pyrogen-free composition for body tissues that are normally not exposed as the basis for packaging the toilet cleaning composition of Kurginski in a sterile, non-pyrogenic form.

As discussed above, Fahim is focused on an antimicrobial handwash composition. To even attempt to combine this teaching with the toilet cleaning composition of Kurginski and the sterile, pyrogen-free composition for body tissues that are normally not exposed of Wider would not be contemplated by those of ordinary skill in the art. Thus, there is no reason for one skilled in the art to package the toilet cleaning composition of Kurginski in a sterile, non-pyrogenic form even in view of the teachings of Fahim and Wider since there is no logical basis for packaging a toilet cleaning composition in a sterile, non-pyrogenic form.

Accordingly, applicants respectfully request that the rejection of claims 32, 34, 37, 41, 42, 45, and 55-60 under § 103(a) as being obvious over Kurginski in view of Fahim and in view of Wider, be withdrawn.

Summary

From a review of each of the combinations of prior art documents, it is evident that the Office has studied applicants' claims, found isolated teachings in the art and attempted to piece them together in an attempt to meet the claimed subject matter. This is manifestly improper as noted by decisions such as *In re Vaeck*, 947 F.2d 448, 20 USPQ2d 1438 (Fed. Cir. 1991) which caution that "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure."

At best, the Office could take the position that it would be obvious to try the combination of prior art documents in the manner hypothesized in the Official Action. However, "obvious to try" is not the standard under 35 U.S.C. §103 as has been held by numerous decisions such as *In re Goodwin*, 198 USPQ 1 (CCPA 1978) and *In re Geiger*, 2 USPQ2d 1276 (Fed. Cir. 1987). All of these decisions have been previously discussed and applicants again assert their applicability without going into detail. Yet further, the positions taken by the Examiner in attempting to piece together disparate teachings in the prior art are contrary to long standing decisions such as *In re Mercier*, 515 F.2d 1161, 1166, 185 USPQ 774, 778 (CCPA 1975) where the court reversed a prior art rejection stating: "The relevant portions of a reference include not only those teachings which would suggest particular aspects of an invention to one having ordinary skill in the art, but also teachings which would lead such a person away from the claimed invention."

Conclusion

In view of the foregoing, further and favorable consideration of the subject application in the form of a Notice of Allowance is respectfully requested.

If there are any questions concerning this response, or the application in general, the Examiner is respectfully requested to telephone applicant's undersigned representative so that prosecution may be expedited.

Respectfully submitted,
BUCHANAN INGERSOLL PC

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By: T. D. Boone
Travis D. Boone
Registration No. 52,635

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620